REMARKS

Claims 1-42 were previously pending in this application. Claims 1-18 and 22-38 have been withdrawn from examination. By this amendment the Applicants are canceling claims 1-18, 22-38 and 39 without prejudice. Applicants have amended claim 19 to add the term "intra-articular." Claim 20 has been amended to correct a typographical error. Support for this amendment can be found at least on page 3, lines 17-19 as well as in the preamble of the claim. As a result claims 19-21 and 40-42 are pending for examination with claim 19 being an independent claim. No new matter has been added.

Telephone Conference

The Applicants would like to thank the Examiner for his courtesy extended to Applicant, Dr. Martha Murray and Applicants' representatives, Helen Lockhart and Marie Jepson during the telephone interview on September 17, 2004. The rejection under 35 USC 103 was discussed with the Examiner. Applicants presented arguments that no motivation to combine the references existed at the time of the invention. Applicants agreed to present evidence of a lack of motivation. Applicants have also incorporated the claim amendment suggested by the Examiner into claim 19.

Rejections Under 35 U.S.C. §112, First Paragraph

The Examiner rejected claim 39 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. According to the Examiner there is no support in the specification for the new limitation "essentially free of exogenous thrombin."

The Applicants have canceled claim 39 without prejudice.

Rejections Under 35 U.S.C. §103

The Examiner rejected claims 19-21 under 35 U.S.C. §103(a) as being unpatentable over Medlen (WO 85/00511) in view of Prior et al. (US 6,096,309). According to the Examiner it would have been obvious to one of ordinary skill in the art to substitute a composition comprising collagen I with a neutralizing agent, platelets and a protein as taught by Prior et al. in

the method of repairing a ligament tear by Medlen in order to provide a more biologically responsive implant capable of controlling blood loss. Applicants respectfully disagree.

One of skill in the art would not have been motivated to combine the composition as taught by Prior et al., with the ligament repair method of Medlen because addition of a hemostatic agent is not useful during ligament repair. Prior et al. describe a composition that is useful for promoting the formation of blood clots for hemostasis (*see 1st sentence abstract, column 1 lines 15-17, column 3, lines 3-10; column 4 lines 6-18 and 64-65, column 12, line 59-column 13, line 40, Examples 2-6 describing effects on hemostasis and example 7 in vivo analysis of hemostasis*). The utility provided by Prior et al for his composition is "hemostasis". Arthroscopic surgery for ligament repair is different from other surgical procedures. This minimally invasive technique requires only small incisions, so little bleeding is encountered. The injured tissue has stopped bleeding long before the surgery, often weeks before. This is different from other surgical procedures where large incisions in vascular tissue results in a great deal of bleeding, where a hemostatic agent might be required. According to the attached Declaration of Dr. Micheli hemostatic agents are not used in ligament surgery. Thus, one of skill in the art would not have been motivated to add a hemostatic agent, such as the material described in Prior et al., to a ligament repair device.

Additionally, even if one of ordinary skill in the art did combine the two references, the combination would not produce the claimed invention. The ligament repair device of Medlen is a collagen based woven like material that is sutured to the ends of the damaged tissue. Prior et al describes a hemostatic agent that is designed to stop bleeding. If one of ordinary skill in the art were to apply a hemostatic agent during surgery it would be applied to exposed blood vessels, not to the damaged ligament or repair device itself. Applicants have discovered that adhesion between the scaffold and the tissue is required to facilitate healing. Contact alone is not enough to be successful. Medlen's woven cloth like material only provides contact with the damaged ligament and not the required adhesion. Contact and adhesion are achieved using the method of claim 19. The hemostatic agent of Prior et al. would be applied to exposed blood vessels and not the repair device of Medlen. Thus, the Prior et al material would not provide the necessary adhesion component because it would not be applied directly to the Medlen device.

It has been discovered according to one aspect of the invention that bleeding should actually be encouraged, not inhibited, during ligament surgery to enhance healing. Prior to the invention it was believed that a hemostatic agent was unnecessary. This discovery of the invention provides further evidence that a hemostatic agent should not be applied during ligament surgery.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner rejected claims 19-20 under 35 U.S.C. §103(a) as being unpatentable over Li et al. (WO 93/21857) in view of Prior et al. (US 6,096,309). According to the Examiner it would have been obvious to one of ordinary skill in the art to add additional components such as platelets and proteins in the collagen material as taught by Prior et al. in the method of repairing a ligament tear by Li et al. in order to provide a more biologically responsive implant capable of controlling blood loss.

Li et al. is directed to a total replacement ligament formed from collagen and not to repairing intra-articular tissue as claimed by the Applicants. Thus, the Li reference does not teach or suggest contacting the ends of ruptured tissues as recited in claim 19. Rather, Li completely replaces ruptured ligament tissue, i.e., attaches the implanted collagen braid from bone to bone.

Even if one of ordinary skill in the art were to combine the references, the combination of these references does not teach Applicants claimed invention. Claim 19 recites that the ends of a ruptured tissue are contacted with the repair material. Li et al. totally replaces the damaged ligament. Li et al does not contact the ends of ruptured tissue with a repair material. Prior et al does not make up for this deficiency. Thus the combination of references does not produce the claimed invention.

One of skill in the art would not have been motivated to combine the teachings of Li et al. describing total replacement of a ligament with the teachings of Prior et al. relating to hemostatic compositions used to stop bleeding. As described above, there is no physiological reason for adding a hemostatic agent to a ligament repair composition. Thus, one of ordinary skill in the art would not have been motivated to combine Prior et al with Li et al.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner rejected claims 39 and 40 under 35 U.S.C. §103(a) as being unpatentable over Medlen (WO 85/00511) in view of Prior et al. (US 6,096,309), and in further view of Bell et al. '292. According to the Examiner it would have been obvious to one of ordinary skill in the art to substitute proteins in the composition and use one such a fibronectin as taught by Bell et al. in the method of Medlen and modified in view of Prior et al. such that it provides a more adhesive like composition to aid in clotting because of the known properties of fibronectin.

One of skill in the art would not have combined the teachings of Medlen with Prior et al. for the reasons described above.

Furthermore, one of skill in the art would not have added the teachings of Bell with Medlen for the following reasons. The implant disclosed in Medlen is attached to the ruptured ends of a ligament *in vivo*, whereas the ligament repair disclosed in Bell is conducted *in vitro*. There is no teaching or suggestion in Bell to suggest that the *in vitro* method or implant components of Bell may be combined with or modified for *in vivo* repair of ligament tissue as in Medlen.

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner rejected claims 41 and 42 under 35 U.S.C. §103(a) as being unpatentable over Medlen (WO 85/00511) in view of Prior et al. (US 6,096,309), and in further view of Weadock (US 6,129,757). According to the Examiner it would have been obvious to one of ordinary skill in the art to incorporate a genetically altered cell in the composition and use one that may relate to clotting as taught by Weadock in the method of Medlen and modified in view of Prior such that it provides the ability to control clotting.

One of skill in the art would not have combined the teachings of Medlen with Prior et al. for the reasons described above.

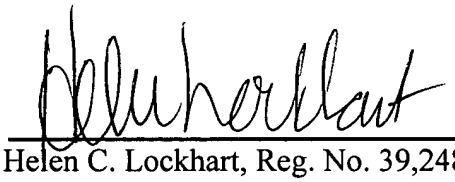
Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
Martha M. Murray, Applicant

By: 

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Docket No. B0801.70258US00
Date: October 4, 2004
x10/13/04x